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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,758	11/20/2001	Todd R. Golub	2825.2024-002	9648

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EXAMINER
GUNTER, DAVID R

ART UNIT	PAPER NUMBER
1634	5

DATE MAILED: 08/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/989,758	Applicant(s) GOLUB ET AL.	
	Examiner David R. Gunter	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 8-10, 15-20, 23 and 24, drawn to a method of classifying a lymphoma sample based on detection of mRNA, classified in class 435, subclass 6.

II. Claims 1-2, 6-10, 15-17, and 21-24, drawn to a method of classifying a lymphoma sample based on detection of protein, classified in class 435, subclass 7.1.

III. Claims 11-14 and 25-28, drawn to a method of assigning a lymphoma sample to a treatment outcome class, classified in class 702, subclass 19.

IV. Claim 29, drawn to an oligonucleotide microarray, classified in class 435, subclass 288.3.

V. Claims 30-36, drawn to a method of assessing treatment efficacy, classified in class 435, subclass 6.

1. Groups I, II, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I recites a method of classifying a lymphoma sample based on the detection of the level of expression of mRNA. Group II recites a method of classifying a lymphoma sample based on the detection of the level of expression of a protein. Detection of a protein requires a substantially different method (mode of operation) than detection of mRNA. For example, detection of a protein requires the use of antibodies specific to the protein of interest while detection of mRNA requires the use of

polynucleotides complementary to the mRNA of interest. Detection of mRNA and detection of protein represent two different functions and effects for the methods of Groups I and II.

The method of Group V recites the additional method steps of treatment of the individual from whom the lymphoma sample was taken and serial assessments of gene expression to assess the efficacy of the treatment. Group V differs from Groups I and II due to the differences in mode of operation (the additional method steps), function (assessment of treatment efficacy vs. classification of the tumor), and effects (production of therapeutic data vs. production of pathologic data). Due to the substantial differences among Groups I, II, and V, the inventions are determined to be unrelated and restriction is deemed proper.

2. Group III is unrelated to Groups I, II and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group III recites the limitations that the expression level of a plurality of molecules will be used in a "weighted voting scheme" to determine the outcome class to which the tumor sample is assigned. Groups I, II, and V are unrelated due to differences among their modes of operation, effects, and functions as described in item 1 above. The additional method steps associated with the weighted voting scheme represent a substantial difference between the mode of operation of Group III and the modes of operation of Groups I, II, and V. For this reason, Group III is determined to be unrelated to Groups I, II, and V, and restriction is deemed proper.

Group IV is related to Groups I – III and V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the detection of gene expression (process) can be practiced with a number of products materially different from oligonucleotide microarray of Group IV (the product) such as northern blots, western blots, or quantitative PCR. Because these inventions are distinct for the reasons given above and the searches required for Group I-III and V are not required for Group IV, restriction for examination purposes as indicated is proper.

Restriction Requirement Applicable to All Groups

In addition to the restriction requirement outlined above, each group reads on patentably distinct groups drawn to multiple polynucleotide sequences as listed in figures 1, 2A, 2B, 3A, 3B, 4A, 4B. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121, and as such are subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

The applicant is required to select one of the five claim groups outlined above for prosecution on its merits.

In addition, the applicants are restricted to a single nucleotide sequence, and must select a single sequence that is compatible with the selected claim group.

The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement, not an election of species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

David R. Gunter, DVM, PhD
August 19, 2002

STEPHANIE W. ZITOMER
PRIMARY EXAMINER